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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,359

07/15/2004

Domenico Fanara

2004_1045A

8158

513 7590 02/13/2008

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

02/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/501,359</p>	<p>Applicant(s) FANARA ET AL.</p>	
	<p>Examiner Lezah W. Roberts</p>	<p>Art Unit 1612</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-3, 5-8, 10-14 and 23-38.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 20 Nov 2007
13. ☐ Other: _____.

/Frederick F. Krass/
Supervisor, Art Unit 1612

Continuation of 3. NOTE: The amended claims incorporate subject matter that raises new issues and would require a further search to determine if the compositions would have been obvious to one of ordinary skill in the art at the time the invention was made. The claims disclose specific polyols such as sorbitol and xylitol, which were not disclosed in the previously presented claims. Mannitol was recited previously but in dependent claims and was not required for the invention of the independent claims. Furthermore the independent claims required at least one polyol and not a mixture as in the currently amended independent claims.

Continuation of 11. does NOT place the application in condition for allowance because: In regards to Andersen in view of Cherukuri, Andersen discloses that the chewing gums encompassed by the reference may include a sugarless coating with a sweetener that is sugarless including mannitol. Cherukuri supports the use of mannitol in coatings of chewing gums by specifically disclosing a sugarless coating comprising mannitol. The claims recite a polyol less than 3000, which encompasses mannitol. There is no recitation in the claims about the polyols reactivity with the compound of formula I or that the molecular weight of the polyol had to be above a certain molecular weight as argued.

In regards to Johnson, although the reference discloses alcohols with a molecular weight no less than 250, it discloses alcohols with a molecular weight no less than 100 and repeats this recitation several times throughout the specification (see the Abstract, page 3, lines 6-8; page 3, line 57 to page 4, line 2; and claim 1). It would not be unreasonable for someone of ordinary skill in the art to use polyols such as mannitol, especially in view of Cherukuri. The reference also discloses "In general, using a greater amount of the hydrophilic polymer decreases the dissolution rate, as does using a higher molecular weight. Using a lower molecular weight polymer increases the dissolution rate. The dissolution rate may also be controlled by the use of water soluble additives such as sugars, salts or soluble polymers. Examples of these additives are sugars such as lactose, sucrose, or mannitol, salts such as sodium chloride, potassium chloride, sodium carbonate, and water soluble polymers such as poly(N-vinyl-2-pyrrolidone) or polyvinylpyrrolidone, low molecular weight HPC or HMPC or methylcellulose" (page 6, lines 4-10). The reference appears to teach mannitol may be used in the compositions, specifically in the layer where cetirizine is not included. The alcohols such as mannitol would not be in direct contact with cetirizine and therefore would not appear to react with the cetirizine. Therefore the reference does not teach away from using alcohols such as mannitol.

/Lezah W. Roberts
Patent Examiner, Art Unit 1612